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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,443	03/07/2001	Suneel K. Gupta	ARC 2863 N1	7756

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,443	GUPTA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledge of applicant's Change in Power of Attorney filed 06/22/04, and Request for Continued Examination, Amendment, and Petition for Revival of Abandoned Application filed 03/11/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/11/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does

not provide support for the limitations submitted in the Amendment filed 03/11/03. While at page 10, lines 20-22 of the specification discloses "[T]he dosage from...at a zero order rate of release *over a period of* 24 hours [time]", does not provide support for the limitations "*substantially* zero order", and "over *about* 24 hours". Applicant's attention is called to page 25 of the specification discloses "the dosage from over a prolonged period of time *up to* 24 hours".

Regarding to the limitations "substantially racemic" and "unaffected by meals", it appears that applicant's specification does not provide support for these limitations as well. Further clarification is suggested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the use of the phrase "upon once daily use is characterized by a sustained release therapeutically effective dose up to 25 mg per hour". The language is confusing. Is it the dosage form that releases up to 25 mg/hr? Further clarification is suggested.

Claims 7 and 8 are rejected in the use of the phrase "[A] method for managing dry mouth". What is managing of dry mouth?

Claims 7-12 and 14 are rejected in the use of the limitation "substantially racemic". What is *substantially* racemic? It is either racemic or not a racemic. It is a 1:1 mixture of the two enantiomers of a compound. It is unclear how a racemic mixture can be substantial. See definition at page 168 of The Cassell Dictionary of Chemistry.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Guittard et al. US 5,912,268.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Guittard discloses a controlled release dosage form comprising 240 ng to 650 mg of oxybutynin, its racemate, its R-enantiomer and its S-enantiomer for administration to a patient to provide a plasma concentration of oxybutynin (column 2, lines 31-48; and column 3, lines 29-31, 45-57). The dosage form delivers oxybutynin to the patient at a zero order rate of release over a period of 24 hours (column 5, lines 40-46). Guittard also teaches administering oxybutynin alone for incontinence therapy, increasing the urinary bladder capacity, for diminishing the frequency of uninhibited contractions of the detrusor muscles (relaxing bladder muscles), (see column 3, lines 24-28; and column 4, lines 13-21).

Guittard does not teach the dosage form releases up to 25 mg per hour, and is unaffected by meals. However, it is the position of the examiner that the dosage form taught by Guittard would have the same properties desired by the applicant, *e.g.*, releases up to 25 mg/hr, and is unaffected by meals, because Guittard discloses the use of the same active compound, the same sustained release carrier in the same sustained release dosage form that exhibits a zero order rate of release over a period of 24 hours for the same use, namely, management of incontinence. Products of identical chemical composition cannot have mutually exclusive properties. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or

claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1-6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Baichwal US 5,399,359.

Baichwal discloses a sustained release formulation comprising oxybutynin and sustained release excipient (abstract; and column 1, lines 55-68), which provides a therapeutically effective blood level of the oxybutynin for at least about 24 hours (column 2, lines 1-28). The formulation comprises up to 20 mg of oxybutynin useful for the treatment of bladder instability (column 3, lines 1-9). Baichwal also discloses method for preparing the sustained release formulation by blending the sustained release excipient and the oxybutynin, and then compress into tablet form and the like (column 5, lines 14-44; and examples).

Baichwal does not explicitly teach the sustained release dosage form that releases up to 25 mg per hour, and is unaffected by meals. However, it is the position of the examiner that the dosage form taught by Baichwal would have the same properties desired by the applicant, *e.g.*, releases up to 25 mg/hr, and is unaffected by meals, because Baichwal discloses the use of the same active compound in the same sustained release dosage form that provides a therapeutically effective blood level of oxybutynin for at least about 24 hours, for the same use, namely, management of incontinence. Products of identical chemical composition cannot have mutually exclusive properties. Therefore, if the prior art teaches the identical chemical structure,

the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Aberg et al. US 5,532,278.

Aberg teaches a method for treating urinary incontinence while avoiding concomitant liability of adverse effects including xerostomia (dry mouth), (see abstract; and column 2, lines 1-10). The method comprises administering a therapeutically effective amount of (S)-oxybutynin or a pharmaceutically acceptable salt thereof (HCl), that is substantially free of R enantiomer (abstract; column 2, lines 40-49; and columns 3, lines 48 through column 4, lines 1-6). Oxybutynin is administered in an amount ranges from about 1 mg to about 100 mg, and in a controlled release means and delivery devices (column 3, lines 19-23; and column 4, lines 20-25). The process for preparing oxybutynin dosage form comprises intimately mixing oxybutynin with carriers, and then forming into desired dosage form (column 4, lines 26-41).

Aberg does not explicitly teach the sustained release dosage form that releases up to 25 mg per hour, and is unaffected by meals. However, it is the position of the examiner that the dosage form taught by Aberg would have the same properties desired by the applicant, *e.g.*, releases up to 25 mg/hr, and is unaffected by meals, because Aberg teaches the use of a controlled release device such as those incorporated by reference, including Theeuwes et al. US 4,008,719 (column 4, lines 20-25). Theeuwes discloses a controlled release device that has a rate of release of 20mg/hour, 30 mg/hr,

or 40 mg/hr for over a prolong period of time (see Theeuwes examples 1, 4, 8, and 13). Thus, Aberg discloses the use of the same active compound in the same sustained release dosage form that provides a similar rate of release over a prolong period of time, for the same use, namely, treating urinary incontinence while reducing dry mouth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al. US 5,912,268, in view of Aberg et al. US 5,532,278.

Guittard is relied upon for the reason stated above. Guittard is silent as to the teaching of a method for decreasing the incidence of dry mouth/managing dry mouth. However, Guittard teaches a dosage form that administers of oxybutynin for its therapeutic benefit accompanied by a lessening of possible unwanted side effects. It is

well know in pharmaceutical art that the side effect of oxybutynin treatment is dry mouth. To be more significant, Aberg teaches adverse effects that primarily arise from administration of oxybutynin include xerostomia (dry mouth) (column 2, lines 1-5). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Guittard for decreasing/managing the incidence of dry mouth in view of the teachings of Aberg, because Aberg teaches a method for treating urinary incontinence while avoiding concomitant liability of adverse effects including dry mouth, and because Guittard teaches an oxybutynin dosage form that administers for its therapeutic benefit accompanied by a lessening of possible unwanted side effects. The expected result would be a sustained release dosage form of oxybutynin useful for the treatment of bladder incontinence while reducing the adverse effects of dry mouth.

Pertinent Arts

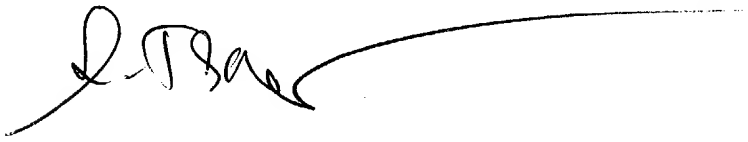
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen et al., Vergez et al., and Malmqvist-Granlund et al. are cited as of interest for the teachings of oxybutynin dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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